

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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In re:

REZULIN PRODUCTS LIABILITY
LITIGATION (MDL No. 1348)

MASTER FILE

00 Civ. 2843 (LAK)

This Document Relates to: 05 Civ. 8397

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MEMORANDUM OPINION

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LEWIS A. KAPLAN, *District Judge.*

This action was brought by Charles A. Foti, Jr., in his official capacity as the Attorney General of the State of Louisiana and as *parens patriae* on behalf of Louisiana and its citizens, the State of Louisiana, and the Louisiana Department of Health and Hospitals (“LDHH”). The matter is before the Court on the motion of defendants Warner-Lambert Company LLC and Pfizer Inc. for summary judgment dismissing the complaint.

Facts

Plaintiff here seeks to recover amounts paid to fill Rezulin prescriptions for Louisiana Medicaid recipients and to treat their illnesses allegedly caused by Rezulin. Their claims are premised on their allegations that Louisiana would not have paid for Rezulin prescriptions filled by Medicaid recipients had it known information that allegedly was withheld or misrepresented by Warner-Lambert and that Louisiana Medicaid recipients would not have used the drug had the State not paid for it. The facts pertinent to this motion, however, are undisputed.¹ As they all relate to the

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Defendants submitted a S.D.N.Y. Rule 56.1 Statement that is supported by admissible evidence properly referred to therein. Plaintiffs’ opposition to defendants’ Rule 56.1 statement in some cases purports to dispute statements in defendants’ filing (¶¶ 1, 4) and in another instance to dispute relevancy and admissibility (¶ 3). In no case do plaintiffs cite admissible evidence demonstrating the existence of a genuine issue of fact for trial as required by S.D.N.Y. Civ. R. 56.1(d). The failure to do so results in the well supported factual assertions in defendants’ statement being deemed admitted. *E.g., Archie Comic Publ’ns, Inc. v. DeCarlo*, 258 F. Supp.2d 315, 317-19 (S.D.N.Y. 2003), *aff’d*, 88 Fed.Appx. 468 (2d Cir.), *cert. denied*, 543 U.S. 813 (2004).

Even if the Court were to consider paragraph 1 of plaintiffs’ Rule 56.1 opposition notwithstanding the lack of evidentiary support, the statements there set forth would not create a genuine issue of fact as to the proposition asserted by defendants, viz. that “Rezulin was a prescription drug that was approved as safe and effective for the Treatment of Type 2 diabetes by the Federal Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act.”

legal framework of the Medicaid program, they are discussed below.

Discussion

The Merits

Louisiana's Legal Obligation to Pay for Rezulin

Federal statutory provisions regulating Medicaid govern what can be included in or excluded from State Medicaid formularies. They also mandate the medications for which Louisiana is required to pay and the exclusive circumstances under which it could refuse such payment. Under those provisions and Louisiana statutes enacted to implement them, the State of Louisiana was required to pay to fill Rezulin prescriptions for Louisiana Medicaid recipients.

Medicaid is a federal program established in 1965 as part of the Social Security Act to provide medical assistance, including the cost of prescription drugs, to low-income individuals and their families by authorizing federal grants to States to accomplish that purpose.² To participate in the Medicaid program and receive federal funding, States must comply with a comprehensive

Paragraph 4 of plaintiffs' Rule 56.1 opposition purports to dispute defendants' allegation that "[p]rior to 2001 Louisiana had an open formulary law which required Medicaid reimbursement of all FDA approved legend drug and none of the exemptions applied to Rezulin." The text of plaintiffs' statement disputes only that Rezulin was a "legend drug" and whether the FDA uses that term. But defendants have submitted a report of the LDHH that states that "[p]rior to 2001 Louisiana had an open formulary law which required Medicaid reimbursement of all FDA approved legend drugs, with a few exceptions." Grass Decl. Ex. B, at 1. That report is of unquestioned admissibility. As plaintiffs have submitted no evidence to the contrary, the quoted statement in the report is deemed admitted for purposes of this motion. Moreover, it is immaterial whether the FDA used the term "legend drug."

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42 U.S.C. § 1396, *et seq.*; 42 C.F.R. § 430, *et seq.*

federal statutory and regulatory scheme.³

Under 42 C.F.R. § 431.10(b), States must provide the federal government with a detailed plan of operation that, among other things, specifies “a single State agency established or designated to administer or supervise the administration of the [Medicaid] plan.” Louisiana has designated LDHH to administer the Medicaid program in Louisiana.

The LDHH was created in 1988 to “be responsible for the development and providing of health and medical services for the prevention of disease for the citizens of Louisiana” and to provide “health and medical services for the uninsured and medically indigent citizens of Louisiana.”⁴ In Louisiana, the LDHH is the sole agency designated to administer the Medicaid program. The program is directed by the Secretary of the LDHH.⁵

The Social Security Act has a detailed statutory and regulatory framework that sets forth specific requirements for Medicaid programs, such as that administered by the LDHH, which received federal funding. Under federal law, a “covered outpatient drug” is one “which may be dispensed only upon prescription” and “which is approved for safety and effectiveness as a prescription drug” under the Federal Food, Drug and Cosmetic Act (the “FDCA”).⁶ At all times,

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Wilder v. Va. Hosp. Ass'n, 496 U.S. 498, 502 (1990) (“Although participation in the program is voluntary, participating States must comply with certain requirements imposed by the Act and regulations promulgated by the Secretary of Health and Human Services”).

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LA. REV. STAT. ANN. § 36:251.

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Id. § 36:254.

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42 U.S.C. § 139r-8(k)(2)(A)(i).

while it was marketed, Rezulin was a prescription drug that was approved as safe and effective for the treatment of Type II diabetes by the FDA under the FDCA.⁷ Thus, Rezulin was a “covered outpatient drug.”

Federal law expressly limits a State’s ability not to pay for “covered outpatient drugs” under the Medicaid programs.⁸ Under federal law, a “State may establish a formulary if the formulary meets” certain specified requirements.⁹ Among those requirements is that the formulary must “[i]nclude[] the covered outpatient drugs of any manufacturer which has entered into and complies” with a rebate agreement with the Secretary of Health and Human Services.¹⁰ To have its drugs qualify for Medicaid reimbursement, federal law requires that a manufacturer enter into a “rebate agreement” with the Secretary of Health and Human Services pursuant to which the manufacturer pays rebates in statutorily mandated amounts to States based on Medicaid sales of its covered outpatient drugs.¹¹ At all times while Rezulin was marketed, Warner-Lambert was a party to a “rebate agreement” with the Secretary of Health and Human Services,¹² which made Rezulin eligible for Medicaid reimbursement.

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In re Rezulin Prods. Liab. Litig., 210 F.R.D. 61, 63 (S.D.N.Y. 2002).

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42 U.S.C. § 1396r-8(d)(1)(B).

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42 U.S.C. § 1396r-8(d)(4).

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42 U.S.C. § 1396r-8(d)(4)(B).

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42 U.S.C. § 1396r-8(a)(1), 1396r-8(b)(1)(A), 1396r-8(c).

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Grass Decl. Ex. A.

Rezulin was withdrawn from the market in the United States on March 21, 2000.¹³

Prior to June 13, 2001, however, the applicable Louisiana statute provided, in pertinent part, that:

“(2) The department shall provide reimbursement for any drug prescribed by a physician that, in his professional judgment and within the lawful scope of his practice, he considers appropriate for the diagnosis and treatment of the patient.

“(3) The department shall not establish a drug formulary that restricts by any prior or retroactive approval process a physician’s ability to treat a patient with a prescription drug that has been approved and designated as safe and effective by the Food and Drug Administration . . .”¹⁴

Hence, the LDHH could not have had a restricted formulary, *i.e.*, one that excluded Rezulin or other covered outpatient drugs, during any part of the period in which Rezulin was on the market. Nor could LDHH have refused payment for Rezulin because LDHH was prohibited from “establish[ing] a drug formulary that restricts by any prior or retroactive approval process a physician’s ability to treat a patient with a prescription drug that has been approved and designated as safe and effective” by the FDA.¹⁵ Reflective of the requirements of this statutory provision, the March 24, 2005 LDHH

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Complaint ¶ 8.

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LA. REV. STAT. ANN. § 46-153.3(B). An amendment to the statute effective July 2, 1999 has no impact on the pending motion. The statute was amended to permit LDHH to “develop peer-based prescribing and dispensing practice patterns for health care providers who participate in the Louisiana Medicaid program and [to] develop a process to promote such practice patterns through the Drug utilization review Board.” La. R.S. § 46:153(B)(4)(a) (attached as Exhibit D to Grass Declaration). As the amended statute expressly stated: “The intent of this [newly added] Paragraph is to limit aberrant practice patterns upon peer-based practice patterns.” Nothing in the 1999 amendment permitted LDHH to refuse payments for medications prescribed to Louisiana Medicaid recipients based on LDHH’s view of the safety, efficacy or cost of those medications relative to other medications. Indeed, the amended statute expressly provided: “Nothing contained herein shall be interpreted or construed as to interfere with the provisions of paragraph (3) of this Subsection,” which prohibited LDHH from doing those things. Thus, for purposes of this motion, the 1999 amendment made no material changes to the applicable provisions set forth above.

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Id.

report to the Governor and the Legislature stated “prior to 2001 Louisiana had an open formulary law which required Medicaid reimbursement of all FDA approved legend drugs, with a few exemptions”¹⁶ none of which is applicable here.¹⁷ In sum, the State of Louisiana was required by federal and Louisiana law to pay pharmacies for the cost of Rezulin prescriptions for Medicaid recipients.

Louisiana’s Fraud on the Market Theory

Plaintiffs sue entirely on Louisiana state law theories, all of which require proof of causation.¹⁸ They therefore are obliged to adduce admissible evidence that, if credited, would be

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Grass Decl. Ex. B, at 1.

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Act 395 of 2001 deleted § 153.3(B)(2) and replaced § 153(B)(3) with the current § 153.3(B)(2)(a), which allows the LDHH to condition payment on prior authorization as defined by federal law. Act 395 of June 13, 2001, § 153.3(B)(3), 2001 La. Sess. Law Serv. 840 (West). Under federal law, a covered outpatient drug subject to a rebate agreement may be excluded from a State’s formulary “with respect to the treatment of a specific disease or condition for an identified population (if any) only if, based on the drug’s labeling . . . the excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness or clinical outcome of such treatment for such population over other drugs included in the formulary and there is a written explanation (available to the public) of the basis for the exclusion.” 42 U.S.C. § 1396r-8(d)(4)(C). In that event, a State may impose a prior authorization requirement – *i.e.*, decline to pay for prescriptions of the excluded drug unless the Medicaid recipient’s doctor first establishes to the State’s satisfaction that the prescription is necessary for the patient. *See id.* § 1395r-8(d)(4)(D). Prior to the enactment of Act 395 of 2001, which postdated the withdrawal of Rezulin from the market, Louisiana was obliged to reimburse for any prescribed drug and was prohibited from imposing any restrictions, including a prior authorization requirement, on such reimbursement.

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See LA. REV. STAT. ANN. § 9.2800.54(A) (Louisiana Products Liability Act, which governs plaintiffs’ strict liability, failure to warn, and breach of warranty claims, requires proof of “damage proximately caused by” defendants); LA. CIV. CODE ANN. art. 2520 (redhibition claim requires proof that plaintiffs “would not have bought the thing had [they] known of the defect”); LA. REV. STAT. ANN. § 51.1409(A) (Louisiana Unfair Trade Practices Act

sufficient to permit a finding of proximate cause. They argue that they are entitled to recover because defendants misled patients and the medical community concerning the safety and efficacy of Rezulin in consequence of which, they claim, Louisiana was called upon to reimburse for prescriptions that otherwise would not have been written at prices that otherwise could not have been charged. This, as defendants maintain, is “a quintessential fraud-on-the-market” theory.

The fraud-on-the-market theory is a creature of the federal securities laws. As the Second Circuit recognized not long ago, “courts repeatedly have refused to apply the fraud on the market theory to state common law cases despite its widespread acceptance in the federal securities fraud context.”¹⁹ Only this year, the New Jersey Supreme Court reversed a grant of class certification and rejected application of the fraud-on-the market theory in a suit relating to the ethical drug Vioxx in circumstances identical to those at Bar.²⁰ Other cases are to similar effect.²¹ Plaintiffs have given the Court no reason to believe that Louisiana’s Supreme Court would reach a different

requires proof of loss “as a result of the use or employment by another person of an unfair or deceptive method, act or practice”); *Edwards v. Conforto*, 636 So.2d 901, 907 (La. 1993) (unjust enrichment requires proof of “a causal relationship between the enrichment and the impoverishment”).

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Secs. Investor Prot. Corp. v. BDO Seidman, L.L.P., 222 F.3d 63, 73 (2d Cir. 2000).

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Int’l Union of Operating Eng’rs Local No. 68 Welfare Fund v. Merck & Co., 929 A.2d 1076, 1088 (N.J. 2007). *Accord, Heindel v. Pfizer, Inc.*, 381 F. Supp.2d 364 (D. N.J. 2004).

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See, e.g., Oliviera v. Amoco Oil Co., 776 N.E.2d 151, 155 (Ill. 2002); *Weinberg v. Sun Co., Inc.*, 777 A.2d 442 (Pa. 2001); *Ex parte Household Retail Servs., Inc.*, 744 So.2d 871, 880 n.2 (Ala. 1999).

result.²² Plaintiffs' reliance on two RICO decisions by Judge Weinstein²³ therefore is misplaced.²⁴

Finally, plaintiffs seek to draw comfort from the Second Circuit's decision in *DeSiano v. Warner-Lambert Co.*,²⁵ where it upheld the legal sufficiency of a complaint by health benefit plan providers ("HBPs"). But *DeSiano* made clear that it upheld the complaint because the HBP plaintiffs alleged that they themselves had been misled as purchasers of the drug:

"In the instant case, . . . Plaintiffs allege an injury directly to themselves; an injury, moreover, that is unaffected by whether any given patient who ingested Rezulin became ill. Plaintiffs' claim is that the Defendants' wrongful action was their misrepresentation of Rezulin's safety, *and that this fraud directly caused economic loss to them [i.e., to the third-party payers] as purchasers, since they would not have bought Defendants' product, rather than available cheaper alternatives, had they not been misled by Defendants' misrepresentations. Thus the damages – the excess money Plaintiffs paid Defendants for the Rezulin that they claim they would not have purchased 'but for' Defendants' fraud – were in no way 'derivative of damage to a third party.'*"²⁶

Here, in contrast, plaintiffs allege that they were injured because patients and the medical community were misled. The undisputed facts show that Louisiana allegedly was injured only because it was

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As this case rests entirely on state law, the Court is obliged to make its best judgment as to the rule that would be formulated by Louisiana's highest court. *Travelers Ins. Co. v. Carpenter*, 411 F.3d 323, 329 (2d Cir. 2005); *Maska, U.S., Inc. v. Kansa Gen. Ins. Co.*, 198 F.3d 74, 78 (2d Cir. 1999).

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In re Zyprexa Prods. Liab. Litig., 493 F. Supp.2d 571 (E.D.N.Y. 2007); *Schwab v. Philip Morris Cos.*, 449 F. Supp.2d 992 (E.D.N.Y. 2006), *appeal pending* No. 06-4666 (2d Cir. argued July 10, 2007).

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The Court notes the Second Circuit's recognition that the law of proximate cause under RICO differs from that under state law. *DeSiano v. Warner-Lambert Co.*, 326 F.3d 339, 348 (2d Cir. 2003).

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326 F.3d 339.

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Id. at 349 (emphasis added) (footnote omitted).

obligated by law to pay for the drugs prescribed for Medicaid recipients and not because Louisiana itself was deceived. *DeSiano* therefore has no bearing here.

The Claim of Inadequate Discovery

Plaintiffs resist summary judgment also on the ground that they have conducted no discovery in this case and refer also to FED. R. CIV. P. 56(f). These assertions are frivolous.

As an initial matter, plaintiffs served discovery requests which the defendants answered in August 2007. The responses brought to plaintiffs' attention the comprehensive discovery already conducted over a period of years by the Plaintiffs' Executive Committee. Plaintiffs to this day have not indicated any dissatisfaction with defendants' responses.²⁷

Even putting aside the inaccuracy of plaintiffs' claim that there has been no discovery, the fact remains that this case was docketed in this Court on September 28, 2005, over two years ago, pursuant to a Multidistrict Panel transfer. If in fact plaintiffs had conducted no discovery either prior or subsequent to the transfer, they would have had no one to blame but themselves. Their inaction cannot afford a basis for denying or deferring summary judgment.

Even more basically, this Circuit has made crystal clear the showing that is required under Rule 56(f) where a party seeks to avoid the entry of summary judgment on the ground that it believes that more discovery is necessary:

“[A] party resisting summary judgment on the ground that it needs discovery in order to defeat the motion must submit an affidavit showing ‘(1) what facts are sought [to resist the motion] and how they are to be obtained, (2) how those facts are reasonably

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Plaintiffs, on the other hand, responded to defendants' interrogatories by what can be described only as categorical stonewalling. Vicari Decl. Ex. B.

expected to create a genuine issue of material fact, (3) what effort affiant has made to obtain them, and (4) why the affiant was unsuccessful in those efforts.”²⁸

“Indeed, the failure to file such an affidavit is fatal to a claim . . . even if the party resisting the motion for summary judgment alluded to a claimed need for discovery in a memorandum of law.”²⁹

Here, plaintiffs have submitted no Rule 56(f) affidavit. They have not shown what facts are sought to resist the motion and how they are to be obtained. They have made no effort to show how those facts might create a genuine issue of material fact. By their own admission, they have made no effort to obtain them. They have failed utterly to make the requisite showing.

Conclusion

For the foregoing reasons, defendants’ motion for summary judgment dismissing the complaint [00 Civ. 2843 docket item 5030] is granted and the action dismissed.

SO ORDERED.

Dated: November 26, 2007



Lewis A. Kaplan
United States District Judge

(The manuscript signature above is not an image of the signature on the original document in the Court file.)

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Miller v. Wolpoff & Abramson, L.L.P., 321 F.3d 292, 303 (2d Cir. 2003) (quoting *Gurary v. Winehouse*, 190 F.3d 37, 43 (2d Cir. 1999) (internal quotation marks and citations omitted)). *Accord*, e.g., *Concourse Rehabilitation & Nursing Center Inc. v. Whalen*, 249 F.3d 136, 146 (2d Cir. 2001).

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Gurary, 190 F.3d at 43-44.